UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

----------X

LINDSAY B. HOROWITZ,

Plaintiff,

-against-

STRYKER CORPORATION, and HOWMEDICA OSTEONICS CORPORATION d/b/a STRYKER ORTHOPAEDICS,

Defendants.

----------X

MEMORANDUM AND ORDER

Civil Action No.
CV-07-1572(DGT)

Trager, J:

Plaintiff, Lindsay Horowitz ("plaintiff" or "Horowitz"), brings this action against Stryker Corporation ("Stryker") and Howmedica Osteonics Corporation ("Howmedica") d/b/a Stryker Orthopaedics (collectively, "defendants") claiming damages resulting from the implantation of an allegedly defective artificial hip that was marketed, manufactured and distributed by defendants. Defendant Howmedica moves to dismiss plaintiff's complaint pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure arguing that all but one of plaintiff's claims are preempted by the Medical Device Amendments Act ("MDA") to the federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360c et seq. and that her remaining claim is improperly pled. For the reasons set forth below, defendant's motion to dismiss is granted.[1]

[1] Although this motion was brought only on behalf of defendant Howmedica, a wholly owned subsidiary of Stryker, this

Background

(1)

On February 3, 2003, defendants received approval from the United States Food and Drug Administration ("FDA") to distribute the Trident™ Ceramic Acetabular System ("Trident System") in the United States. Pl.'s Am. Compl. ¶ 12. Under the MDA, the Trident System is classified as a Class III medical device. In order for any Class III device to obtain federal approval it must go through a pre-market approval ("PMA") process, in which the FDA analyzes whether the device is reasonably safe and effective. 21 U.S.C. § 360c(a)(1)(C). On obtaining FDA approval, defendants proceeded to develop, manufacture and distribute the Trident System. See Pl.'s Am. Compl. ¶ 4.

Two years later, on February 16, 2005, plaintiff underwent total hip arthroplasty surgery at Lenox Hill Hospital in New York, where the Trident System was implanted in her body. Id. at ¶ 18. Following her surgery, plaintiff began "hear[ing] an audible sound emanating from the location of the [Trident System]." Id. at ¶ 21. According to plaintiff, the sound caused her to experience "constant irritation and discomfort in the location of the artificial hip replacement device." Id. at ¶ 22. She further claims that "[a]s a result of the implantation of the Defective

---

motion will be construed as having been brought on behalf of both defendants because the same arguments apply equally to defendant Stryker.

Device, Plaintiff has suffered additional and resultant bone loss and is at an increased risk for requiring a premature revision surgery." Id. at ¶ 23.

Plaintiff asserts that the Trident System's current federally approved labeling information states that:

> An audible noise during motion, such as a squeak, has been reported for patients receiving a ceramic-on-ceramic bearing couple. A 0.5% rate of squeaking noise has been reported in the clinical study with the Trident® Alumina Insert.

Id. at ¶ 65. However, she claims that she was not informed of these prevalence rates prior to surgery. Id. (alleging that "Defendants [sic] label failed to provide any substantive or quantitative prevalence rates whatsoever to Plaintiff prior to her surgery.").

Plaintiff further alleges that on March 13, 2006 and August 30, 2007, defendants initiated recalls of two batches of Trident PSL HA Solid Back Acetabular Shells. According to plaintiff, the stated reason for the March 13th recall was that:

> Defendants had identified dimensional anomalies in the recalled components . . . due to an alleged discovery of a machine operator's failure to inspect product dimensional features prior to release wherein shells where [sic] found to be out of tolerance.

Pl.'s Am. Compl. ¶ 31. The stated reason for the August 30th recall was that:

> Defendants had identified that "specific lots of Trident PSL Acetabular shells may have a dimensional discrepancy. The deviation regarding the differences in wall thickness will increase the gap between the shell and liner on one

> side and will decrease the gap between shell and liner on the opposing side, resulting in interference."

Id. at ¶ 32. On January 22, 2008, defendants recalled a batch of Trident PSL and Hemispherical Cups manufactured at defendants' Ireland facilities between January 2000 and December 2007 after a deviation was identified between the required specifications and processes for manufacturing. Id. at ¶ 33. Plaintiff admits that neither the Trident System, which is the subject of the current action – nor any of its components – were included in any of these recalls. Id. at ¶ 35 ("[U]pon information and belief, Defendants have failed to properly initiate a recall including Defendants' Defective Devices beyond the limited scope of the above reference [sic] recalls.").

On March 15, 2007 the FDA issued a warning letter to defendants concerning federal regulatory violations it found when it inspected defendants' Ireland facilities between October 31, 2006 and November 3, 2006. See Pl.'s Mem. in Opp'n to Def.'s Mot. to Dismiss ("Pl.'s Opp'n") Ex. A. The inspection revealed that the orthopedic implants manufactured by defendants, including the Trident System:

> [A]re adulterated within the meaning of section 501(h) of the [Federal Food, Drug, and Cosmetic] Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (C.F.R.), Part 820.

Id. at 1.

The FDA issued another warning letter to defendants on November 28, 2007, after finding violations during its inspection of defendants' New Jersey facilities between June 1, 2007 and July 12, 2007. See Pl.'s Opp'n Ex. B. Similar to the previous warning letter, the federal investigation revealed that defendants' hip implants with ceramic bearing components were adulterated within the meaning of 21 U.S.C. § 351(h) in that defendants failed to conform to the Current Good Manufacturing Practice ("CGMP") requirements of the Quality System ("QS") regulation. Pl.'s Opp'n Ex. B at 1. The letter specified, among other things, that defendants received numerous complaints: (1) between January 2005 and May 2007 regarding hip implant components with poor fixation; (2) between January 2005 and April 2007 regarding squeaking noises emanating from hip implants with ceramic bearing components; and (3) between January 2005 and June 2007 regarding improper seating of hip implants in broached bones. Id. at 2. According to the warning letter, defendants violated federal regulations in failing to:

> [E]stablish and maintain procedures for identifying all of the actions needed to correct and prevent the recurrence of nonconforming product and other quality problems, and verifying or validating the corrective and preventive action to ensure that such action is effective.

Id.

(2)

On March 1, 2007, plaintiff filed suit in the Supreme Court of the State of New York. Defendants removed on April 17, 2007, on the basis of federal diversity jurisdiction. On February 14, 2008, plaintiff moved to amend her complaint, and despite defendants' opposition the motion was granted on August 26, 2008.

The Amended Complaint contains eight counts including: (1) failure to warn (strict liability); (2) defective manufacturing (strict liability); (3) defective design (strict liability); (4) negligence and recklessness; (5) breach of express warranty; (6) breach of implied warranty of fitness; (7) breach of implied warranty of merchantability; and (8) violations of New York's General Business Law.[2] In their motion to dismiss defendants argue that: (1) all of plaintiff's claims, aside from her claim for defective manufacturing, are preempted by the MDA; (2) even if plaintiff's express warranty claim and claims under New York's General Business Law are not preempted, they are improperly pled; and (3) plaintiff's defective manufacturing claim is similarly deficient.

---

[2] Plaintiff, in her opposition brief, for the first time, introduced a claim for misrepresentation. See Pl.'s Opp'n at 15. The Second Circuit has held that "[a] party may not use his or her opposition to a dispositive motion as a means to amend the complaint." Shah v. Helen Hayes Hosp., 252 Fed. App'x 364, 366 (2d Cir. 2007) (citing Wright v. Ernst & Young LLP, 152 F.3d 169, 178 (2d Cir. 1998)). Horowitz fails to allege misrepresentation either in her complaint or her amended complaint. Accordingly, this opinion does not consider this claim.

Discussion

Defendants argue that the Supreme Court's recent decision in Riegel v. Medtronic, Inc., ___ U.S. ___, 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008), mandates that all of plaintiff's claims with the exception of her claim for defective manufacturing, are preempted. Riegel involved an FDA approved balloon catheter that ruptured in the plaintiff's coronary artery because the doctor inflated the device beyond its rated burst pressure. Riegel, 128 S. Ct. at 1005. The plaintiff and his wife brought suit alleging that the catheter was designed, labeled and manufactured in violation of New York common law and that such defects caused him to suffer severe and permanent injuries. Id. at 1005. The catheter, like the Trident System, was a Class III device approved through the PMA process. Id. at 1005. The plaintiffs asserted a number of claims based on violations of New York common law duties, including strict liability, breach of implied warranty and negligence in the manufacture, design, testing, inspection, distribution, labeling, marketing and sale of the catheter. Id. at 1006. The Supreme Court held that the plaintiffs' state law products liability claims were preempted by the MDA as they "fell within the core of the MDA's pre-emption provision because they sought to impose different requirements on precisely those aspects of the device that the FDA had approved." Altria Group, Inc. v. Good, ___ U.S. ___, 129 S. Ct. 538, 549, ___ L. Ed. 2d ___ (2008)

(discussing Riegel).

The Court left open the possibility that state law claims found to be "parallel" to the federal regulations could be sustained. Riegel, 128 S. Ct. at 1011 (finding that Section 360k did "not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations" because in such a case the state duties would "'parallel,' rather than add to, federal requirements"); see also In re Medtronic, MDL No. 08-1905, ___ F. Supp. 2d ___, 2009 WL 35467, at *3 (D. Minn. Jan. 5, 2009) (confirming that "Riegel left open a back door for plaintiffs: claims alleging that a manufacturer failed to adhere to the specifications imposed by a device's PMA are not preempted."). However, because the plaintiffs in Riegel neglected to raise the parallel regulation argument, either before the lower court or in their petition for certiorari, the Supreme Court declined to address whether their causes of action were actually parallel to the federal requirements. Riegel, 128 S. Ct. at 1011. In the instant case, Horowitz argues that because her claims are premised on defendants' numerous federal violations, the parallel regulation exception applies to save her action from dismissal. Horowitz further contends that even under the Supreme Court's ruling in Riegel, her claims for breach of express warranty, defective manufacturing and violations of New York's General Business Law are not subject to preemption since they are not common law claims

challenging the safety and effectiveness of the Trident System.

(1)

The Pre-Market Approval Process

The Medical Device Amendments established the regulatory regime for medical devices, which are categorized into one of three classes depending on the risk they pose to the public. See 21 U.S.C. § 360c. Class I devices are subject to "general controls," the lowest level of review, and include devices such as elastic bandages and examination gloves. § 360c(a)(1)(A); Riegel, 128 S. Ct. at 1003. Class II devices are subject to "special controls," and include devices such as powered wheelchairs and surgical drapes. § 360c(a)(1)(B); Riegel, 128 S. Ct. at 1003. Class III devices, on the other hand, are subject to the PMA process, the highest level of federal review, and include devices like replacement heart valves, implanted cerebella stimulators and pacemaker pulse generators. § 360c(a)(1)(C); Riegel, 128 S. Ct. at 1004. "In general, a device is assigned to Class III if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness, and the device is 'purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health,' or 'presents

a potential unreasonable risk of illness or injury.'" Riegel, 128 S. Ct. at 1003 (quoting § 360c(a)(1)(C)(ii)).

Before any new Class III medical device can be marketed or sold, it must first receive FDA approval through the rigorous PMA process. That process was established to ensure that a medical device is reasonably safe and effective prior to it being exposed to the public. See Riegel, 128 S. Ct. at 1004. In deciding whether to grant PMA approval, the FDA "weigh[s] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." § 360c(a)(2)(C). If the benefit the device provides is substantial enough, the FDA may approve the device despite the risks it may pose. Riegel, 128 S. Ct. at 1004. FDA approval is, therefore, no guarantee that the product is completely safe from harmful defects. See Clark v. Medtronic, Inc., 572 F. Supp. 2d 1090, 1094 (D. Minn. 2008)(stating that "[p]laintiff is ultimately wrong when he assumes that premarket approval guarantees the device is completely safe."). The FDA also reviews the device's proposed label to ensure that it is neither false nor misleading. Riegel, 128 S. Ct. at 1004. Once a medical device is approved through the PMA process, no change in design, manufacturing or labeling, which would affect safety or effectiveness, may be made without additional FDA approval. Id. at 1005. Following approval, the manufacturer must inform the FDA if it becomes aware of adverse results in patients using the advice.

21 C.F.R. §§ 803.50, 803.53.

Medical device manufacturers must also follow the FDA's CGMP requirements set forth in the QS regulation, which "govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use." 21 C.F.R. § 820.1(a)(1). However, the FDA recognizes that these requirements "are intended to serve only as 'an umbrella quality system,' providing 'general objectives' medical-device manufacturers must seek to achieve." In re Medtronic, 2009 WL 35467, at *8 (quoting FDA Device Advice, Good Manufacturing Practices (CGMP)/Quality System (QS) Regulation, available at http://www.fda.gov/cdrh/devadvice/32.html#flexibility (last visited January 2, 2009)). They do not specifically address the design, production and marketing requirements for each and every type of medical device. Id. The CGMP requirements, therefore, leave it up to the manufacturer to institute a quality control system specific to the medical device it produces to ensure that such device is safe and effective.

(2)

Preemption Under the Medical Device Amendments

The MDA includes a preemption provision, which states that:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

§ 360k(a). The FDA is in the unique position of being the only entity with the authority to approve a new medical device. If a state were permitted to impose either different or additional requirements on a federally approved medical device, it would disrupt the safety/effectiveness determination already conducted by the FDA. See Carter v. Novartis Consumer Health, Inc., 582 F. Supp. 2d 1271, 1281 (C.D. Cal. 2008).

In analyzing whether a claim is preempted by the MDA, a court must make three determinations. First, it must find that federal requirements are imposed on the particular medical device. Riegel, 128 S. Ct. at 1006. If so, then the court must determine whether the plaintiff's claims are based on a state requirement that "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device." Id. at 1007 (quoting § 360k(a)). Finally, such claims will be preempted where they impose requirements that are either different from, or in addition to, the federal regulations. Id.

With respect to the first issue in the instant case, federal

requirements are imposed specifically on the Trident System. Neither party disputes that the Trident System is a Class III device, which was approved through the FDA's PMA process. As described above, the PMA process is a form of federal safety review. The review is device specific, requiring applicants to submit, among other things, specifications for the device's components and properties, a description of the method used in manufacturing the device and an example of the proposed label for the device. § 360e(c)(1). During review, the FDA balances competing interests regarding the specific device's risks and benefits and then implements its conclusion in the form of mandates directed at the manufacturer and producer of the specific medical device. Mitchell v. Collagen Corp., 126 F.3d 902, 911 (7th Cir. 1997). Finally, once approved, the manufacturer may not deviate from the specifications as they existed at the time it went through the PMA process. Riegel, 128 S. Ct. at 1007. Any changes either from the medical device's specifications or to any of conditions to the original approval must be approved by the FDA. See § 360e(d)(6)(A)(i). It is clear, therefore, that federal requirements attach specifically to the Trident System, which has successfully completed this rigorous process. See Riegel, 128 S. Ct. at 1007 (stating that "premarket approval is specific to individual devices.").

As to the second determination, plaintiff's claims for strict

liability, negligence and recklessness, and breach of express[3] and implied warranties all concern violations of state requirements relating "to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device," making them subject to preemption. § 360k(a)(2). The Court in Riegel, found that state imposed requirements include both state common law duties as well as state statutory requirements. Riegel, 128 S. Ct. at 1008. The Court reasoned that allowing a plaintiff to obtain relief on a state tort cause of action could force manufacturers to alter their medical device as already approved by the FDA. Any modification made to a federally approved device, such as the Trident System, could potentially impact its safety and effectiveness as already established by the PMA process. Id. at 1008 ("State tort law that requires a [medical device] to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect.").

The current motion hinges on the third issue - whether plaintiff's state law claims are parallel to the federal requirements already imposed on the Trident System. What is clear after Riegel is that claims which impose "liability as to a

[3] As discussed below, plaintiff's breach of express warranty claim is subject to preemption only to the extent that the claim stems from the representations made on the Trident System's label.

PMA-approved medical device, notwithstanding that device's adherence to the standards upon which it obtained premarket approval from the FDA, are preempted." Riegel v. Medtronic, Inc., 451 F.3d 104, 106 (2d Cir. 2006), aff'd, 128 S. Ct. 999 (2008). However, if plaintiff's state common law claims are premised on the device's failing to comply with FDA standards, then they are parallel. Riegel, 128 S. Ct. at 1011.

Plaintiff's generalized allegations cannot withstand preemption because they fail to establish the necessary link between defendants' federal violations and her alleged causes of action. Plaintiff asserts in her opposition papers that "it is anticipated that there will be additional violations alleged regarding the Defendants' breaches of federal regulations that correlate with the state duties alleged in the Amended Complaint." Pl.'s Opp'n at 9. To survive a motion to dismiss plaintiff must plead enough facts "to state a claim to relief that is plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 127 S. Ct. 1955, 1974, 167 L. Ed. 2d 929 (2007). A "formulaic recitation of the elements of a cause of action will not do." Twombly, 127 S. Ct. at 1965. Instead, the "[f]actual allegations must be enough to raise a right to relief above the speculative level." Id. Plaintiff's factual allegations must be sufficient to "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." Twombly, 127 S. Ct. at 1964 (quoting Conley

v. Gibson, 355 U.S. 41, 47, 78 S. Ct. 99, 2 L. Ed. 2d 80 (1957)). Plaintiff's mere promises of future factual allegations are not sufficient to meet this standard.

In an effort to satisfy the pleading standard and bring forth facts demonstrating the parallel nature of her claims, Horowitz points to two warning letters issued by the FDA. However, such letters do not provide the necessary connection to the specific Trident System at issue in this case.

A similar tactic was employed by the plaintiffs in two recent cases involving claims for injuries caused by the Trident System - both of which rejected the argument. In Bausch v. Stryker Corp., No. 08 C 4248, 2008 WL 5157940 (N.D. Ill. Dec. 9, 2008), the court found that the plaintiff's strict liability claims were preempted by the MDA. The court reasoned that simply alleging that the defendants violated federal regulations did not necessarily mean that the plaintiff's strict liability claim was premised on those violations.[4] Bausch, 2008 WL 5157940, at *4 (finding that the

[4] With regard to the plaintiff's negligence claim, the Bausch court found that state law claims are preempted by the MDA even where they are based on conduct that constitutes a violation of federal regulations as long as they are "different" from the federal regulations. Bausch, 2008 WL 5157940, at *5. Adopting this view means that a plaintiff's state law claim could only survive preemption where it is "based on a duty that is 'substantially identical' to the duty that is imposed on the Trident [System] by FDA regulations." Bausch, 2008 WL 5157940, at *6. This is at odds with the Supreme Court's decision in Riegel, which used the word "parallel" to describe the types of state law claims that are excepted from the MDA's preemption provision. Riegel, 128 S. Ct. 1011. All that is required for a

plaintiff's "inclusion of separate allegations in her complaint that Defendants violated regulations of the FDA does not make her strict liability claim premised in any way on those violations and, thus, parallel to the regulatory scheme of the federal government"). Another case involving the Trident System brought in the District of Colorado also rejected the plaintiff's parallel regulation argument. See Parker v. Stryker Corp., 584 F. Supp. 2d 1298 (D. Colo. 2008). There, the court found that the plaintiff's complaint was deficient in that it failed to provide any factual detail substantiating her claim that the Trident System was defective as a direct result of defendants having manufactured it in violation of the PMA process. Id. at 1301-02.

In Purcel v. Advanced Bionics, No. 07-CV-1777, 2008 WL 3874713 (N.D. Tex. Aug. 13, 2008), which did not involve the Trident System, the court found that the plaintiffs' strict liability and breach of implied warranty of merchantability claims were not preempted by the MDA. Purcel involved a federally approved Class III cochlear ear device, known as HiRes90k, which was manufactured by the defendant Advanced Bionics Corporation ("Bionics") and

---

state law claim to bypass preemption is that it not be in conflict with the federal regulation. See Purcel v. Advanced Bionics Corp., No. 07-CV-1777, 2008 WL 3874713, at *3 (N.D. Tex. Aug. 13, 2008)("The dispositive issue is not whether [state] tort law duties are, in the abstract, 'different from, or in addition to' the federal requirements applicable to Class III devices, but whether the Plaintiffs are asserting claims under state law which impose requirements different from those arising under federal law." (emphasis in original)).

implanted in the minor plaintiff's ears in 2005. Purcel, 2008 WL 3874713, at *1. The lawsuit centered on a feed-thru component manufactured by co-defendant Astro Seal, Inc. ("Astro"). Id. The specific cochlear devices implanted in the minor plaintiff were discovered to have contained moisture levels well above those provided in the manufacturing specifications approved by the FDA. Id. The plaintiffs thus brought an action alleging that Bionics violated federal regulations by not informing the FDA that Astro, a different company from the one Bionics used when its device received FDA approval, was now supplying it with the feed-thru component. Purcel, 2008 WL 3874713, at *1. Most importantly, they alleged that it was the new supplier's modifications to the feed-through component that caused the excessive moisture levels and the plaintiff's injury. Id. The court found that the plaintiffs' strict liability claims were not preempted by the MDA as they were predicated solely on violations of federal law. Id. at *3. Similarly the plaintiffs' breach of implied warranty of merchantability claim was found to be parallel to federal regulations since the defendant's compliance with the applicable federal requirements would have prevented state law liability. Id. at *4.

The Purcel decision does not conflict with the holdings in Bausch and Parker. All three decisions show that in order to survive preemption under the MDA a plaintiff must demonstrate a

cognizable link between the defendant's federal violations and plaintiff's injury. As evidence that their claims were based principally on federal violations, the plaintiffs in Purcel pointed to device specific violations: (1) inspection reports and warning letters issued by the FDA to Bionics, documenting federal violations between 2001 and 2005 focusing on moisture problems, Purcel, 2008 WL 3874713, at *1; (2) a voluntary recall issued by Bionics concerning all HiRes90k devices that contained the feed-through component manufactured by Astro, id.; and (3) an FDA enforcement action against Bionics and its President and CEO for violations of CGMP and premarket approval requirements as a result of the company's failure to notify the FDA of the change in supplier and failing to validate the continued safety and effectiveness of the cochlear implant, id. at *2.

In the present action plaintiff lacks such a tie to the device in question. Although plaintiff cites to recalls instituted by defendants, such recalls did not include the Trident System or any of its components. Plaintiff introduces FDA warning letters mentioning defendants' violations of federal regulations, but she never alleges that her particular product was included in the devices which were the subject of those letters nor does she provide a necessary link between the federal violations and her specific injury. Finally, plaintiff never alleges that any enforcement action was brought against defendants concerning the

allegedly defective hip implant. Looking at each of plaintiff's claims individually provides a better understanding of why more than a majority of her claims fail on preemption grounds.

(3)

Negligence/Recklessness & Defective Manufacturing

The FDA letters introduced in plaintiff's complaint state that two separate inspections revealed that, for certain periods of time, medical devices manufactured by defendants in their New Jersey and Ireland facilities, including the Trident System, were adulterated. Specifically, defendants were cited for violations of the Current Good Manufacturing Practice requirements of the Quality System regulation and for failing to take corrective measures after being informed of problems with medical devices they manufacture. "[C]laims that a manufacturer has violated the MDA in some respect do not diminish or impair the applicability of the doctrine of federal preemption." Lake v. Kardjian, No. 03-1267, ___ N.Y.S.2d ___, 2008 WL 5244823, at *2 (N.Y. Sup. Ct. Madison County Dec. 17, 2008).

Instead, to proceed with her claim, plaintiff must demonstrate that the particular federal violation led to the injuries she sustained. This is a burden that plaintiff cannot meet. Plaintiff provides no explanation as to how her Trident System, which was

implanted in her body in 2005, relates to investigations conducted by the FDA in 2006 and 2007. Her complaint also fails to specify in which of defendants' facilities her hip replacement device, or any components included in the device, was manufactured, making it unclear which, if either, of the two letters she is using to substantiate her claims. "Plaintiff[] cannot simply incant the magic words '[Howmedica] violated FDA regulations' in order to avoid preemption." In re Medtronic, MDL No. 08-1905, ___ F. Supp. 2d ___, 2009 WL 35467, at *9 (D. Minn. Jan. 5, 2009).

Plaintiff has failed to demonstrate that the injuries she sustained resulted from the federal violations spelled out in the warning letters. In order to survive a motion to dismiss, a complaint must "amplify a claim with some factual allegations in those contexts where such amplification is needed to render the claim plausible."[5] Iqbal v. Hasty, 490 F.3d 143, 157-58 (2d Cir.

---

[5] Plaintiff brings attention to a recent decision where the district court denied defendants' motion to dismiss similar claims arising out of alleged injuries caused by the Trident System. Hofts v. Howmedica Osteonics Corp., No. 08-CV-0855, ___ F. Supp. 2d ___, 2009 WL 331470 (S.D.Ind. Feb. 11, 2009). The court found that the plaintiff's allegations that Howmedica failed to meet the FDA's requirements were sufficient, by themselves, to withstand preemption at the motion to dismiss stage. Id. at 5. Requiring the plaintiff to plead his claims with more specificity, according to the Hofts court, would amount to an unusually stringent application of Twombly. Id. at 6. On the contrary, requiring amplification as to how the defendants' alleged federal violations relate to the plaintiff's claims is exactly what Twombly contemplates, especially where such a connection is implausible.

2007) (emphasis in original). The generalized allegations made in plaintiff's complaint call for such amplification here as the relationship between defendants' federal violations and plaintiff's injury seems implausible. See, e.g., Heisner v. Genzyme Corp., No. 08-C-593, 2008 WL 2940811, at *5 (N.D. Ill. July 25, 2008) (finding that "Plaintiff's vague suggestion that Defendant violated [FDA] reporting requirements does not help Plaintiff avoid dismissal of his claims; Plaintiff has not alleged anything in his complaint that would put Defendant on notice that the basis of Plaintiff's claim was [Defendant's] failure to meet reporting requirements.").

Plaintiff's negligence/recklessness claim cannot withstand preemption as it is not premised on a federal violation. "[N]egligence claims must be considered preempted to the extent that they allege that [the manufacturer] was negligent despite its adherence to the standards required by the FDA in its PMA for this specific product." Mitchell v. Collagen Corp., 126 F.3d 902, 913 (7th Cir. 1997). Plaintiff fails to allege any facts demonstrating that the federal violations described in the warning letters resulted in plaintiff's Trident System being manufactured in violation of the PMA process. Thus, for plaintiff to be successful in her negligence/recklessness claim a jury would have to find that the FDA requirements themselves were deficient. See Rollins v. St. Jude Med., 583 F. Supp. 2d 790, 797 (W.D. La. 2008). Such a finding would directly interfere with the PMA process.

Plaintiff's defective manufacturing claim fails for the same reason, as it is simply a restatement of her negligence claim. "To plead and prove a manufacturing flaw under either negligence or strict liability, the plaintiff must show that a specific product unit was defective as a result of 'some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction,' and that the defect was the cause of plaintiff's injury." Colon ex rel. Molina v. BIC USA, Inc., 199 F. Supp. 2d 53, 85 (S.D.N.Y. 2001) (quoting Caprara v. Chrysler Corp., 52 N.Y.2d 114, 129, 417 N.E.2d 545, 552-53, 436 N.Y.S.2d 251, 258 (1981)). Plaintiff must, therefore, show that her specific hip replacement device was defective. The amended complaint's generic allegations of a defective manufacturing claim, much like the negligence claim, do not demonstrate that they are based on defendants' violation of federal regulations. See Stevens v. Pacesetter, Inc., No. 07-CV-3812, 2008 WL 2637417, at *1 (D.S.C. April 1, 2008) (finding that although "[t]he complaint contains a few generic allegations of a manufacturing defect[,] [t]hese allegations do not, however, suggest that the particular alleged failure is a failure to manufacture the device in accordance with federal standards." (emphasis in original)). Additionally, plaintiff's "reliance on [defendants' violations of] CGMPs and QSR . . . does not save these claims from preemption . . . [as such requirements] are simply too generic, standing alone, to serve as

the basis for [her] manufacturing-defect claim[]." In re Medtronic, 2009 WL 35467, at *8. Without more specific allegations explaining how defendants' manufacturing process was in violation of federal requirements so that the device was defective, plaintiff's claim falls directly within the MDA's preemption provision.

(4)

Defective Design

Plaintiff's design defect claim is also preempted. "Under New York law, a design defect may be actionable under a strict products liability theory if the product is not reasonably safe." Denny v. Ford Motor Co., 87 N.Y.2d 248, 256-57, 662 N.E.2d 730, 735, 639 N.Y.S.2d 250, 255 (1995). "[A] defectively designed product is one which, at the time it leaves the seller's hands, is in a condition not reasonably contemplated by the ultimate consumer and is unreasonably dangerous for its intended use; that is one whose utility does not outweigh the danger inherent in its introduction into the stream of commerce." Robinson v. Reed Prentice Div. of Package Mach. Co., 49 N.Y.2d 471, 479, 403 N.E.2d 440, 443, 426 N.Y.S.2d 717, 720 (1980). Plaintiff's defective design claim, which challenges the FDA's findings concerning the safety of the Trident System's design, necessarily imposes requirements that are

different from, or in addition to, federal regulations. See Berish v. Richards Med. Co., 928 F. Supp. 185, 191-92 (N.D.N.Y. 1996)(stating that courts have reasoned that "'the extensive, premarket regulatory scheme applicable to Class III devices, because of the devices' "potential unreasonable risk of illness or injury," imposes requirements relating to design and manufacture that would preempt state law claims relating to the same.'")(quoting Elbert v. Howmedica, Inc., 841 F. Supp. 327, 330 (D. Haw. 1993)), reconsideration in part, 937 F. Supp. 181, 186 (N.D.N.Y. 1996) (permitting plaintiff's negligent manufacturing claim to proceed only "to the extent that the plaintiff has alleged a claim that the defendant failed to comply with a federal regulation").

(5)

Breach of Implied Warranty

In order to recover under a breach of implied warranty of merchantability claim plaintiff must establish that the Trident System was not "reasonably fit for the ordinary purpose for which it was intended." Denny, 87 N.Y.2d at 265. The FDA warning letters never imply, and plaintiff never alleges, that defendants' federal violations caused the Trident System to be unfit in assisting patients in walking, which is the purpose for which the

Trident System was created. For plaintiff to succeed on her claim, a jury would have to find that defendants breached the implied warranty of merchantability by manufacturing a medical device that was unsafe in its federally approved design or manufacture. In re Medtronic, 2009 WL 35467, at *14. Such a claim falls squarely within the MDA's preemption provision.[6] Plaintiff's breach of the implied warranty of fitness claim fails for the same reason. See N.Y. U.C.C. § 2-315.

(6)

Breach of Express Warranty

Plaintiff's breach of express warranty claim is preempted to the extent that it is premised on FDA approved representations made by the manufacturer. Lake v. Kardjian, No. 03-1267, ___ N.Y.S.2d ___, 2008 WL 5244823, at *2 (N.Y. Sup. Ct. Madison County Dec. 17,

---

[6] In Hofts v. Howmedica Osteonics Corp., in addressing the plaintiff's breach of implied warranty claims, the district court found that "[t]he FDA's own regulations explicitly restrict the reach of the MDA's preemption clause from state law claims brought under regulations of general applicability including the Uniform Commercial Code." 2009 WL 331470, at *8. The Hofts court ignores, however, that Riegel explicitly rejected that the regulation alters the outcome of the case, reasoning that such an interpretation would effectively swallow the preemption rule. Riegel, 128 S. Ct. at 1011 ("The Riegels' reading of § 808.1(d)(1), however, would allow a claim for tortious mislabeling to escape pre-emption so long as such a claim could also be brought against objects other than medical devices.").

2008) (finding that "a breach of express warranty claim based upon FDA approved statements in product labeling and advertising is preempted by the MDA, because such a claim would impose requirements different from, or in addition to, the federal requirements, potentially resulting in the imposition of liability on a manufacturer who has fully complied with federal law."). "To permit a jury to decide [the plaintiff's] claims that the information, warnings, and training material the FDA required and approved through the PMA process were inadequate under state law would displace the FDA's exclusive role and expertise in this area and risk imposing inconsistent obligations on [defendants]." Rollins, 583 F. Supp. 2d at 797-98 (quoting Gomez v. St. Jude Med. Daig Div.,Inc., 442 F.3d 919, 931 (5th Cir. 2006)). In a related action alleging similar injuries resulting from the implantation of the Trident System, Parker v. Stryker Corp., 584 F. Supp. 2d 1298 (D. Colo. 2008), the court concluded that the plaintiff's breach of express warranty claim was preempted, reasoning that permitting the claim to go forward "would contradict the FDA's determination that the representations made on the label were adequate and appropriate and, thus, impose requirements different from or in addition to the federal requirements." Id. at 1303.

In her complaint, plaintiff broadly alleges that "Defendants

expressly represented and warranted that Defective Device[7] was safe." Pl.'s Am. Compl. ¶ 106. Plaintiff seems to be referring to the representations made on the Trident System's FDA approved label, which states that "[a]n audible noise during motion, such as a squeak, has been reported for patients receiving a ceramic-on-ceramic bearing couple." and that "[a] 0.5% rate of squeaking noise has been reported in the clinical study with the Trident® Alumina Insert." Id. at ¶ 65. In order to avoid preemption, the plaintiff's breach of express warranty claim must "identify specific representations of the manufacturer which exceed the scope of the FDA approved statements, thereby establishing a contractual obligation voluntarily entered into by the manufacturer." Lake, 2008 WL 5244823, at *2. Any claim for breach of express warranty premised on the Trident System's FDA-approved label, however, must be preempted.

If plaintiff's breach of express warranty claim is based on non-FDA-approved representations, although such a claim would survive preemption, it would still ultimately fail here. In New York, representations which are the subject of breach of express warranty claims are considered to be requirements imposed by the warrantor, not by the state. Wallace v. Parks Corp., 212 A.D.2d 132, 138, 629 N.Y.S.2d 570, 574 (4th Dep't 1995)(finding that

[7] Plaintiff's breach of express warranty claim fails even to refer to the Trident System by its name, instead referring to it simply as the "Defective Device."

liability under "[b]reach of express warranty claims . . . arises not from a requirement imposed by State law, but from a promise voluntarily made by the manufacturer.") (citing Cipollone v. Liggett Group, Inc., 505 U.S. 504, 525 (1992)). An express warranty is an "affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain." N.Y. U.C.C. § 2-313(1)(a); see Friedman v. Medtronic, Inc., 42 A.D.2d 185, 190, 345 N.Y.S.2d 637, 643 (2d Dep't 1973). Under New York law, an action for breach of express warranty requires both the existence of an express promise or representation and reliance on that promise or representation. See CBS Inc. v. Ziff-Davis Publ'g Co., 75 N.Y.2d 496, 503, 553 N.E.2d 997, 1000-01, 554 N.Y.S.2d 449, 452-53 (1990).

Nowhere in her amended complaint does plaintiff allege that she relied on defendants' alleged representation that the Trident system was "safe."[8] Plaintiff does not even describe how this

[8] In a recent action involving the Trident System, the U.S. District Court for the District of New Jersey permitted the plaintiff's breach of express warranty claim to proceed. Huber v. Howmedica Ostenics Corp., No. 07-2400, 2008 WL 5451072 (D.N.J. Dec. 31, 2008). The court reasoned that the plaintiff's claim did not conflict with the MDA's preemption provision since Third Circuit precedent holds that "a breach of express warranty does not implicate a state action (but is rather a voluntary commitment between two contracting parties) and does not seek to enforce a requirement different from, or in addition to, federal requirements." Id. at *4. The court further found that the plaintiff's breach of express warranty claim was sufficiently pled because of the plaintiff's allegation regarding the existence of evidence showing that the .5% defect rate printed on the Trident System's label is actually much higher and that the

representation was made. Without sufficient allegations identifying the conduct at issue, plaintiff has failed to give the defendants notice of the grounds of her claim. Her claim for breach of express warranty must, therefore, be dismissed. See, e.g., Lake, 2008 WL 5244823, at *2 ("[P]laintiff has not identified any specific statements by [the defendant] which would constitute an express warranty, and has thereby failed to establish the existence of a claim which would escape federal preemption and survive this motion to dismiss.").

(7)

Failure to Warn

Plaintiff claims that defendants failed to properly warn her about the risk of an audible noise emanating from the Trident System. Such a claim would clearly impose requirements different from, or in addition to, the federal regulations. The warning letters make no reference to a finding by the FDA that the Trident System's label violated federal requirements. Plaintiff's failure to warn claim is thus an attack on the Trident System's federally

---

defect rate was a basis of the bargain. Id. at *4. In the current action, not only does Horowitz fail to allege that the Trident System's label contained an error regarding the stated defect rates, she asserts in her complaint that she was not informed of the defect rates prior to her surgery. See Pl.'s Am. Compl. ¶ 35. Horowitz cannot now argue that the defect rates were a basis of the bargain.

approved label. Allowing the claim to proceed would permit a jury to find that defendants were required "to provide warnings above and beyond those on the [Trident System's] product label - a label that was specifically approved by the FDA as part of the PMA process." In re Medtronic, 2009 WL 35467, at *10. Accordingly, plaintiff's failure to warn claim is preempted.[9] Brahman v. Baxter Healthcare Corp., 842 F. Supp. 747, 758 (S.D.N.Y. 1994)(confirming that "[i]n light of [the MDA's] explicit labeling provisions, the courts have found federal preemption of state claims based on a duty to warn theory.").

(8)

New York General Business Law

Plaintiff fails to state a valid claim under New York's General Business Law ("NYGBL"). Section 349 of the NYGBL proscribes that "[d]eceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service in this state are hereby declared unlawful." N.Y. Gen. Bus. Law

[9] Even if plaintiff's failure to warn claim was somehow able to survive preemption, New York's learned intermediary doctrine provides that "the manufacturer of a medical device does not have a duty to directly warn a patient of risks associated with the device, but instead discharges its duty by providing the physician with sufficient information concerning the risks of the device." Sita v. Danek Med., Inc., 43 F. Supp. 2d 245, 259 (E.D.N.Y. 1999). By providing adequate warnings on the Trident System's label, defendants fulfilled any duty to warn owed to plaintiff.

§ 349(a). To establish a claim under § 349, the plaintiff must allege that "a defendant is engaging in consumer-oriented conduct which is deceptive or misleading in a material way, and that plaintiff has been injured because of it." Weiss v. Polymer Plastics Corp., 21 A.D.3d 1095, 1097, 802 N.Y.S.2d 174, 176 (2d Dep't 2005) (citing Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank, 85 N.Y.2d 20, 25, 647 N.E.2d 741, 744, 623 N.Y.S.2d 529, 532 (1995)). Deceptive acts are defined as those that are "likely to mislead a reasonable consumer acting reasonably under the circumstances." Oswego Laborers' Local 214 Pension Fund, 85 N.Y.2d at 26. Section 350 of the NYGBL proscribes "[flse advertising in the conduct of any business, trade or commerce." N.Y. Gen. Bus. Law § 350. To establish a false advertising claim under § 350, "[a] plaintiff must demonstrate that the advertisement (1) had an impact on consumers at large, (2) was deceptive or misleading in a material way, and (3) resulted in injury." Andre Strishak & Assocs., P.C. v. Hewlett Packard Co., 300 A.D.2d 608, 609, 752 N.Y.S.2d 400, 403 (2d Dep't 2002).

Plaintiff generally alleges that "Defendants' acts, representations and/or omissions constitute unconscionable commercial practices in connection with the sale of merchandise and false advertising and were deceptive and misleading practices." Pl.'s Am. Compl. ¶ 124. With regard to plaintiff's § 349 claim, plaintiff makes no reference to the specific "acts, representations

and/or omissions" that she claims are deceptive nor does she allege why these acts were deceptive. "Plaintiff may not maintain a cause of action under General Business Law § 349 where . . . she has failed to identify any 'material' 'deceptive acts' engaged in by the defendant." Benjaminov v. Republic Ins. Group, 241 A.D.2d 473, 474, 660 N.Y.S.2d 148, 149 (2d Dep't 1997). Even if the deceptive or misleading conduct she refers to has something to do with the FDA's findings described in the warning letters and defendants' failure to reveal such information to plaintiff, Horowitz provides no connection between the defendants' deceptive conduct and a specific injury that she suffered as a result of that activity. See Bogosian v. All American Concessions, No. 06-CV-1633, 2008 WL 4534036, at *4 (E.D.N.Y. Sept. 30, 2008) ("Defendants should not be required to infer from the pleadings the critical facts and the operative legal standard underlying a claim [under General Business Law Section 349]."). In order to make a claim under NYGBL Section 350, a plaintiff must plead reliance on a false advertisement at the time the product was purchased. See Andre Strishak, 300 A.D.2d at 610 (affirming dismissal of § 350 cause of action because "plaintiffs failed to show that they relied upon or were aware of the allegedly false advertisement when purchasing the [product]"). Similar to plaintiff's breach of express warranty claim, plaintiff never specifies what false representations defendants made nor does she allege that she ever relied on any representations made by

defendants. Moreover, using the NYGBL to attack the Trident System's FDA-approved label would run afoul of the MDA's preemption provision. Accordingly, plaintiff's claims for violations under the NYGBL are dismissed.

Conclusion

For the forgoing reasons, defendants' motion to dismiss is granted. Plaintiff's claims for failure to warn and defective design are dismissed with prejudice. Plaintiff's remaining claims are dismissed with leave to replead.

Dated: Brooklyn, New York
February 20, 2009

SO ORDERED:

/S/
David G. Trager
United States District Judge